

§ 524.86

21 CFR Ch. I (4-1-96 Edition)

524.1982 Proparacaine hydrochloride ophthalmic solution.  
524.2101 Selenium disulfide suspension.  
524.2140 Squalane, pyrethrins and piperonyl butoxide.  
524.2350 Tolnaftate cream.  
524.2481 Triamcinolone acetonide cream.  
524.2620 Liquid crystalline trypsin, Peru balsam, castor oil.  
524.2640 Tylosin, neomycin eye powder.

AUTHORITY: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

SOURCE: 40 FR 13873, Mar. 27, 1975, unless otherwise noted.

**§ 524.86 Amitraz liquid.**

(a) *Specifications.* Amitraz liquid contains 19.9 percent amitraz in an organic solvent.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Indications for use.* For dogs for the treatment of generalized demodicosis (*Demodex canis*).

(2) *Amount.* One 10.6 milliliter bottle per 2 gallons of warm water (250 parts per million) for each treatment, for a total of 3 to 6 treatments, 14 days apart.

(3) *Limitations.* Continue treatment until no viable mites are found in skin scrapings at 2 successive treatments, or until 6 treatments have been applied. Do not use for treatment of localized demodicosis or scabies. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 18589, Apr. 30, 1982]

**§ 524.154 Bacitracin or bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment.**

(a) *Sponsor.* To firms identified in § 510.600(c) of this chapter as follows:

(1) To 000009; each gram contains 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B.

(2) To 011716 and 025463; each gram contains 400 units of bacitracin zinc, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B sulfate.

(b) *Conditions of use. Dogs and Cats.* (1) *Amount.* Apply a thin film over the cornea 3 or 4 times daily.

(2) *Indications for use.* Treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to susceptible organisms.

(3) *Limitations.* Laboratory tests should be conducted including in vitro culturing and susceptibility tests on samples collected prior to treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992; as amended at 61 FR 8873, Mar. 6, 1996]

**§ 524.155 Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment.**

(a) *Sponsor.* To firms identified in § 510.600(c) of this chapter as follows:

(1) To 011716; each gram of ointment contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone.

(2) To 025463; each gram of ointment contains 400 units of bacitracin zinc, 10,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), and 10 milligrams of hydrocortisone acetate.

(b) *Conditions of use. Dogs and cats.* (1) *Amount.* Apply a thin film over the cornea three or four times daily.

(2) *Indications for use.* For treating acute or chronic conjunctivitis caused by susceptible organisms.

(3) *Limitations.* All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992; as amended at 61 FR 8873, Mar. 6, 1996]

**§ 524.321 Cephalonium, polymyxin B sulfate, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride topical-otic ointment.**

(a) *Specifications.* Each gram of the drug contains 10 milligrams cephalonium, 5,000 units polymyxin B sulfate, 0.25 milligram flumethasone, 30 milligrams iodochlorhydroxyquin, and